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CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER

WHITEMAN, BRIAN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/079,609

Applicant(s)

KOCHANЕК ET AL.

Examiner

Brian Whiteman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9,10 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/21/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### **Non-Final Rejection**

Claims 1-21 are pending examination.

#### ***Election/Restrictions***

Applicant's election of Group I (claims 1-10) and PEDF as species in Paper filed on 11/20/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

NOTE: the election is moot for superoxide dismutase (Groups III and VIII) and alpha-mannosidase (Groups IV and IX) for examination in paper filed 11/20/03 because these species are in a non-elected group.

An iris pigment epithelial cell in claim 2 and claims 7, 8, and 11-20 and an anti-angiogenetic factor, anti-oxidative factor, lysosomal factor, vasodilating factor in claim 3 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions and GDNF, NGF, BDNF, CNTF, bFGF or neurotrophin 3, neurotrophin 4, and neurotrophin 5 in claim 3 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed on 11/20/03.

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***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

Reichel's article in German in the information disclosure statement filed 10/21/02 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

The article labeled IOVS: 39: 719 1998 in the information disclosure statement filed on 10/21/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. A copy of page 719 has not been provided by the applicants. In addition, the citation of the article on the PTO-1449 does not fully comply with the requirements of 37 CFR 1.98 because: the author of the article is missing. The article has been placed in the application file, but the information referred to therein has not been considered.

***Drawings***

The drawings were received on 2/21/02. These drawings are acceptable.

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### ***Specification***

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The disclosure is objected to because of the following informalities: the heading for several sections is missing, e.g., BACKGROUND OF THE INVENTION.

Appropriate correction is required.

*Claim Objections*

Claims 1-6, 9, 10 and 21 are objected to because of the following informalities: the phrase is “a pigment epithelial cell of the eye as claimed in claim 1” is grammatically improper phrase for a dependent claim.

Suggest amending the phrase to recite -- the pigment epithelial cell of the eye as claimed in claim 1 --.

Claims 4 and 21 are objected to because of the following informalities: the term “and/or” is considered an improper Markush language term. MPEP 2173.05(h) recites, “When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively.”

Claim 5 is objected to because of improper Markush language. A therapeutic protein and a therapeutic RNA do not belong to a recognized physical or chemical class or to an art-recognized class. The specification does not disclose that a therapeutic protein and a therapeutic RNA possess at least one common property. MPEP 2173.05(h) recites:

The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed

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relationship, and it is clear from their very nature or from the prior art that all of them possess this property.

Claim 6 is objected to because of improper Markush language. A cell is in a fixed assemblage of cells; cultivated in the presence of a feeder layer; serum-free medium do not belong to a recognized physical or chemical class or to an art-recognized class. The specification does not disclose that the processes possess at least one common property. See MPEP 2173.05(h).

Claim 10 is objected to because of improper Markush language. Cultivating a cell in the presence of a feeder layer and cultivating a cell in serum-free medium do not belong to a recognized physical or chemical class or to an art-recognized class. The specification does not disclose that the processes possess at least one common property. See MPEP 2173.05(h).

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9, 10, and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pigment epithelial cell of the eye comprising an adenoviral vector with large DNA capacity comprising a nucleic acid operatively linked to a

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promoter, does not reasonably provide enablement for a pigment epithelial cell of the eye comprising an adenoviral vector with large DNA capacity lacking a promoter operatively linked to a nucleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Furthermore with respect to claimed invention, the claims embrace using a pigment epithelial cell of the eye, which comprises an adenoviral vector with large DNA capacity to express at least one nucleic acid. The specification provides sufficient guidance for one skilled in the art to make and use an adenoviral vector comprising a nucleic acid operatively linked to a promoter. However, the specification fails to provide sufficient guidance or evidence for one skilled in the art to make and use an adenoviral vector, which expresses a nucleic acid product, wherein the nucleic acid is not operatively linked to a promoter in the vector. The teachings in the specification are directed to using a promoter to express a nucleic acid product. See pages 10-11. The as-filed specification provides sufficient guidance and/or evidence for how to make and use adenoviral vectors comprising a promoter operatively linked to a nucleic acid to direct expression of the nucleic acid product, however the claims do not recite such a structural limitation. Thus, to the extent the claims fail to recite distinguishing features to commensurate with the level of guidance presented, the claims are not considered enabled.

In conclusion, the as-filed specification and claims coupled with the state of the art at the time the invention was made only provide enablement for using a pigment epithelial cell of the eye comprising an adenoviral vector with large DNA capacity comprising a nucleic acid operatively linked to a promoter. However, the rest of the disclosure encompassing an



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adenoviral vector comprising a promoter not operatively linked to a nucleotide sequence from the vector is not considered enabled for the reasons set forth above. Given that making an adenoviral vector, which expresses protein(s) comprising a promoter not operatively linked to a nucleotide sequence in the vector was unpredictable at the time the invention was made, and given the lack of sufficient guidance for producing the claimed pigment epithelial cell, one skilled in the art would have to engage in a large quantity of experimentation in order to practice the full scope of the claimed invention based on the applicants' disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a nucleic acid encoding a protein operatively linked to a promoter in the adenoviral vector. The specification recites, "after transduction of the pigment epithelial cell with an adenoviral vector with large DNA capacity, the cell is able to produce therapeutic proteins or RNAs." See page 12, lines 19-21. In view of the specification, the omitted elements are required for the cell to produce at least one therapeutic protein and/or a therapeutic RNA.

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*Claim Rejections - 35 USC § 102*

NOTE: the recitation “has been cultivated in the presence of a feeder layer and/or in serum-free medium” in the claim 6 has no patentable weight because the patentability is based on the product itself.

MPEP 2113 recites: “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 3, 4, 5, 6, 9, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Kovesdi et al., (US 2003/0045498). Kovesdi teaches administering an adenoviral vector comprising a nucleic acid sequence encoding a pigment epithelium-derived factor (PEDF) to

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retinal pigment epithelial cells (abstract, pages 2, 3, 4, 6, 15, and 16). Kovesdi teaches that the adenoviral vector is deficient in genes essential for viral replication such that the vector can accept large inserts of exogenous DNA (pages 4-5). Kovesdi teaches that any promoter can be used in the vector, e.g., constitutive, regulatable, tissue-specific (pages 6-7). Kovesdi teaches a pharmaceutical composition comprising the vector and using the vector to study treatment of ocular disorders (pages 12 and 13).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovesdi et al., (US 2003/0045498) taken with Tezel et al., (Exp. Eye Res. (1998) 66, 807-815).

Kovesdi teaches administering an adenoviral vector comprising a nucleic acid sequence encoding a pigment epithelium-derived factor (PEDF) to retinal pigment epithelial cells (abstract, pages 2, 3, 4, 6, 15, and 16). Kovesdi teaches that the adenoviral vector is deficient in genes essential for viral replication such that the vector can accept large inserts of exogenous DNA (pages 4-5). Kovesdi teaches that any promoter can be used in the vector, e.g., constitutive, regulatable, tissue-specific (pages 6-7). Kovesdi teaches a pharmaceutical composition comprising the vector and using the vector to study treatment of ocular disorders (pages 12 and 13). However, Kovesdi does not specifically teach culturing the genetically modified retinal pigment epithelial cell (RPE) of the eye in serum-free media.

However, at the time the invention was made, Tezel teaches that serum-free media can be used for culturing RPE cells (page 807). Tezel further teaches culturing the cells onto tissue-culture plastic pre-coated with bovine corneal endothelial extracellular matrix (page 807). Tezel teaches, "The presence or absence of serum-derived hormones, cytokines, carrier proteins, cell attachment factors and cell spreading factors can have a profound effect on the behavior of RPE cells in tissue culture and may mask the specific effects of a particular exogenous cytokine(s) on RPE. For these reasons, several researchers have cultured RPE with reduced or not serum

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supplementation (page 807).” “This is particularly important for RPE, because RPE cells exhibit phenotypic heterogeneity (page 812).”

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kovesdi taken with Tezel to culture genetically modified retinal pigment epithelial cells in serum-free media. One of ordinary skill in the art would have been motivated to culture the RPE cells in serum-free media because Tezel teaches that culturing RPE cells in serum free medium avoids the effect of hormone, cytokines, carrier proteins, cell attachment factors and cell spreading factors on the behavior of RPE cells in tissue culture.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovesdi et al., (US 2003/0045498) taken with Funk et al., (US 6,667,176) in further view of Williams et al., (Nature, 1988, 336:684-7).

Kovesdi teaches administering an adenoviral vector comprising a nucleic acid sequence encoding a pigment epithelium-derived factor (PEDF) to retinal pigment epithelial cells (abstract, pages 2, 3, 4, 6, 15, and 16). Kovesdi teaches that the adenoviral vector is deficient in genes essential for viral replication such that the vector can accept large inserts of exogenous DNA (pages 4-5). Kovesdi teaches that any promoter can be used in the vector, e.g., constitutive, regulatable, tissue-specific (pages 6-7). Kovesdi teaches a pharmaceutical composition comprising the vector and using the vector to study treatment of ocular disorders

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(pages 12 and 13). However, Kovesdi does not specifically teach culturing the genetically modified retinal pigment epithelial (RPE) cell of the eye in the presence of a feeder layer.

However, at the time the invention was made, Williams teaches that maintenance of stem-cell phenotype *in vitro* requires the presence of a feeder layer (page 684).

In addition, at the time the invention was made, Funk teaches that RPE cells are progenitor cells (column 17, lines 34-57).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kovesdi taken with Williams and Funk to culture genetically modified retinal pigment epithelial cells in the presence of a feeder layer. One of ordinary skill in the art would have been motivated to culture the RPE cells in the presence of a feeder layer because Williams teaches that culturing stem cells in the presence of a feeder layer maintains stem-cell phenotype *in vitro* and Funk teaches that RPE cells are progenitor cells.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovesdi et al., (US 2003/0045498) taken with Funk et al., (US 6,667,176) and Williams et al., (Nature, 1988, 336:684-7) in further view of Tezel et al., (Exp. Eye Res. (1998) 66, 807-815).

Kovesdi teaches administering an adenoviral vector comprising a nucleic acid sequence encoding a pigment epithelium-derived factor (PEDF) to retinal pigment epithelial cells (abstract, pages 2, 3, 4, 6, 15, and 16). Kovesdi teaches that the adenoviral vector is deficient in

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genes essential for viral replication such that the vector can accept large inserts of exogenous DNA (pages 4-5). Kovesdi teaches that any promoter can be used in the vector, e.g., constitutive, regulatable, tissue-specific (pages 6-7). Kovesdi teaches a pharmaceutical composition comprising the vector and using the vector to study treatment of ocular disorders (pages 12 and 13). However, Kovesdi does not specifically teach culturing the genetically modified retinal pigment epithelial (RPE) cell of the eye in a serum-free medium and in the presence of a feeder layer.

However, at the time the invention was made, Williams teaches that maintenance of stem-cell phenotype in vitro requires the presence of a feeder layer (page 684). In addition, Funk teaches that RPE cells are progenitor cells (column 17, lines 34-57).

Furthermore, at the time the invention was made, Tezel teaches that serum-free media can be used for culturing RPE cells (page 807). Tezel further teaches culturing the cells onto tissue-culture plastic pre-coated with bovine corneal endothelial extracellular matrix (page 807). Tezel teaches, "The presence or absence of serum-derived hormones, cytokines, carrier proteins, cell attachment factors and cell spreading factors can have a profound effect on the behavior of RPE cells in tissue culture and may mask the specific effects of a particular exogenous cytokine(s) on RPE. For these reasons, several researchers have cultured RPE with reduced or not serum supplementation (page 807)." "This is particularly important for RPE, because RPE cells exhibit phenotypic heterogeneity (page 812)."

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Kovesdi taken with Williams and Funk in further view of Tezel to culture genetically modified retinal pigment epithelial cells in serum-

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free medium and in the presence of a feeder layer. One of ordinary skill in the art would have been motivated to culture the RPE cells in the presence of a feeder layer because Williams teaches that culturing stem cells in the presence of a feeder layer maintains stem-cell phenotype *in vitro* and Funk teaches that RPE cells are progenitor cells. In addition, one of ordinary skill in the art would have been motivated to use serum-free medium in the method because Tezel teaches that culturing RPE cells in serum free medium avoids the effect of hormone, cytokines, carrier proteins, cell attachment factors and cell spreading factors on the behavior of RPE cells in tissue culture.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

### ***Conclusion***

If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that the copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application



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is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

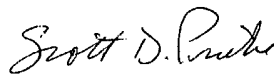
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman  
Patent Examiner, Group 1635

  
SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER